

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 42D1089402	(X3) Date Survey Completed 04/09/2026
Name of Provider or Supplier Midlands Neurology Pain & Associates, Pa	Street Address, City, State 2601 Milwood Avenue, Columbia, SC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An on-site validation survey was conducted on April 09, 2026 with the following standard level deficiencies cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: I. Based on direct observation, manufacturer's instructions, review of the laboratory's temperature records, and interview with the Laboratory Director (LD), the laboratory failed to define temperature ranges in accordance with manufacturer instructions for 2 of 2 years (2024 and 2025). Findings Included: 1) During a tour of the laboratory at 2:30 PM on 4/09/2026, the following instruments were observed in operation on the laboratory benchtop: a. Horiba Micros 60 Hematology Analyzer, Serial Number 207CS100375, Manufacturer temperature requirements 18 to 25 degrees Celsius. b. Horiba Pentra 400 Chemistry Analyzer, Serial Number 212C4-1469, Manufacturer temperature requirements 18 to 25 degrees Celsius. 2) Review of the laboratory's temperature records sheet titled 'Midlands Neurology and Pain Associates ABX Pentra C400 Standard Operating Procedures Temperature/Humidity Chart' showed an acceptable room temperature range of 17 to 24 degrees Celsius. 3) In an interview at 2:35 PM on 4/09/2026 in the conference room, the LD confirmed the lower threshold of the acceptable room temperature range was not defined in</p>

accordance with manufacturer instructions. II. Based on direct observation, review of manufacturer's instructions, laboratory temperature records, and interview with the Laboratory Director (LD), the laboratory failed to define, monitor and document room temperature for the phlebotomy room for 2 of 2 years (2024 and 2025). Findings Included: 1) During a tour of the laboratory at 2:30 PM on 4/09/2026, the following temperature dependent blood tubes were observed on the shelves and storage cabinet available for use: a. 200 Becton Dickinson (BD) EDTA, Purple Top Vacutainer Tubes, Lot Number 4344072, Manufacturer storage temperature requirements 4 to 25 degrees Celsius b. 100 BD EDTA K2, Blue Top Vacutainer Tubes, Lot Number 5293144, Manufacturer storage temperature requirements 4 to 25 degrees Celsius c. 500 BD Clot Activator Red/Yellow Top Tubes, Lot Number B25053F5, Manufacturer storage temperature requirements 4 to 25 degrees Celsius 2) The laboratory could not provide room temperature records of monitoring and documenting room temperature in the phlebotomy room for 2024 and 2025. 3) In an interview at 2:32 PM on 4/09/2026 in the phlebotomy room, the LD confirmed the findings the laboratory did not define, monitor or document temperatures in the phlebotomy room. III. Based on review of the laboratory's policies and procedures, temperature and humidity records, manufacturer's instructions and interview with the Laboratory Director (LD), the laboratory failed to define freezer temperatures and humidity for 10 of 12 months (Random review January 1 to December 31, 2025). Findings Included: 1) Review of the laboratory's policy titled 'Midlands Neurology & Pain Acceptable Temperature Ranges Policy #480' stated " ...Criteria is established for the proper storage of reagents and specimens ...Freezer -20 degrees Celsius or colder; Hygrometer (Humidity) 40-80% Non-Condensing". 2) Review of the laboratory's acceptable freezer temperature ranges on the log sheet revealed a range of -10 to -30 degrees Fahrenheit. 3) Review of the laboratory's acceptable humidity range on the log sheet revealed a range of 40 to 80% in January and February 2025, and 20 to 80% from March 2025 to December 2025. 4) Review of the Horiba Pentra C400 and Micros 60 analyzer manufacturer humidity requirements stated 20 to 85% and "Up to 80%". Both humidity settings in 2025 were within the manufacturer required range. 5) In an interview on 4/07/2026 at 2:32 PM, the LD confirmed the freezer temperature ranges were not defined in accordance with the policy and were not in the correct unit of measurement. She also confirmed the humidity range on the log sheet was changed in March 2025, but not reflected in the policies and procedures.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
 Based on direct observation, review of quality control (QC) records, laboratory test records, and confirmed in an interview with the Laboratory Director (LD), the laboratory failed to take corrective action(s) necessary to ensure the evaluation of all patient test results obtained since the last acceptable test run after QC failures requiring recalibration on the Horiba Pentra C400 for 3 of 65 testing days (random review July 1, 2025 to September 31, 2025). Findings Included: 1) During a tour of

the laboratory at 2:30 PM on 4/09/2026, one Horiba Pentra C400 analyzer, Serial Number 212C4-1469, was observed in use. 2) Review of the laboratory's QC records from July to September 2025 (random review), revealed the following QC failures with subsequent recalibration where evaluation of patient results since the last acceptable test run was not performed: a. Ethanol (ETOH) - QC Failure requiring recalibration on 7/23/2025; 21 Patients tested for ETOH in last acceptable test run (7/22/2025): 250722004U, 250722011U, 250722001U, 250722002U, 250722003U, 250722005U, 250722006U, 250722007U, 250722008U, 250722009U, 250722010U, 250722012U, 250722013U, 250722014U, 250722015U, 250722016U, 250722017U, 250722018U, 250722019U, 250722020U, 250722021U b. Oxycodone (OXY) - QC Failure requiring recalibration on 8/23/2025; 20 Patients tested for OXY in last acceptable test run (8/21/2025): 250821004U, 250821011U, 250821001U, 250821002U, 250821003U, 250821005U, 250821006U, 250821008U, 250821013U, 2508210023U, 2508210025U, 250821007U, 250821009U, 250821010U, 250821012U, 250821014U, 250821015U, 250821016U, 250821017U, 250821018U c. Cocaine (COC) - QC Failure requiring recalibration on 9/10/2025; 20 Patients tested for COC in last acceptable test run (8/20/2025): 250909009U, 250909001U, 250909002U, 250909003U, 250909004U, 250909005U, 250909006U, 250909007U, 250909008U, 250909010U, 250909011U, 250909012U, 250909015U, 250909016U, 250909019U, 250909021U, 250909024U, 250909013U, 250909014U, 250909017U 3) In an interview at 2:35 PM on 4/09/2026 in the conference room, the LD confirmed the QC failures with subsequent recalibrations performed and lack of patient evaluations to the last acceptable test run.